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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,919	02/17/2005	Amato J Giaccia	35045 PCT USA	1460

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,919	GIACCIA ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to A truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, classified in class 530, subclass 350.

II. Claims 8, drawn to an isolated nucleic acid encoding a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, classified in class 536, subclass 23.1.

III. Claims 9-13, drawn to a method of inhibiting adipogenesis comprising: contacting a cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPAR.gamma.2 promoter activity, wherein expression of PPAR.gamma.2 is reduced and adipogenesis is inhibited, classified in class 435, subclass 7.1.

IV. Claims 14-18, drawn to a method of inhibiting PPARgamma2 promoter activity comprising contacting a cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, classified in class 435, subclass 7.1.

V. Claims 19-24, drawn to a method of inhibiting angiogenesis in a tumor comprising: contacting the tumor with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPARgamma2 promoter activity, wherein expression of PPARgamma2 is reduced and angiogenesis is inhibited, classified in class 514, subclass 12.

VI. Claims 25-28, drawn to a method of inhibiting angiogenesis in an angiogenesis related disease comprising: contacting at least one cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPAR.gamma.2 promoter repressing activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPAR.gamma.2 promoter activity, wherein expression of PPARgamma2 is reduced and angiogenesis is inhibited, classified in class 514, subclass 12.

VII. Claims 29-31, drawn to a method of identifying a DEC1/Stra13 agonist comprising: contacting a test compound with a cell comprising a reporter gene operably linked to a PPARgamma2 proximal promoter fragment; and comparing reporter gene expression in the presence of the test compound with reporter gene expression in the presence of a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPAR.gamma.2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, wherein reporter gene expression that is about the same indicates a DEC1/Stra13 agonists, classified in class 435, subclass 7.1.

VIII. Claims 32-33, drawn to a method of identifying a PPARgamma2 agonist comprising: contacting a test compound with a mammalian cell comprising a functional PPARgamma2 gene; and comparing the amount of PPARgamma2 polypeptide in the presence of the test compound with the amount of PPARgamma2 polypeptide in the presence of a known PPARgamma2 agonist, wherein reporter gene expression that is about the same indicates that the test compound is a PPARgamma2 agonist, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule

and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I and III-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product such as the process of making antibodies

The product of the invention of Group II is not used in the method of the invention of Groups III-VIII, thus the inventions are patentably distinct.

Inventions III and IV-VIII, IV and V-VIII, V and VI-VIII, VI and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects The invention of Group III is a method of inhibiting adipogenesis comprising: contacting a cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing

activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPAR.gamma.2 promoter activity, wherein expression of PPAR.gamma.2 is reduced and adipogenesis is inhibited, the invention of Group IV is a method of inhibiting PPARgamma2 promoter activity comprising contacting a cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, the invention of Group V is a method of inhibiting angiogenesis in a tumor comprising: contacting the tumor with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPARgamma2 promoter repressing activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPARgamma2 promoter activity, wherein expression of PPARgamma2 is reduced and angiogenesis is inhibited, the invention of Group VI is a method of inhibiting angiogenesis in an angiogenesis related disease comprising: contacting at least one cell with a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPAR.gamma.2 promoter repressing activity as full-length DEC1/Stra13 polypeptide in an amount sufficient to repress PPAR.gamma.2 promoter activity, wherein expression of PPARgamma2 is reduced and angiogenesis is inhibited, the invention of Group VII is a method of identifying a DEC1/Stra13 agonist comprising: contacting a test compound with a cell comprising a reporter gene operably linked to a PPARgamma2 proximal promoter fragment; and comparing reporter gene expression in the presence of the test

compound with reporter gene expression in the presence of a truncated DEC1/Stra13 polypeptide lacking the DEC1/Stra13 repressor domain wherein the truncated polypeptide has substantially the same PPAR.gamma.2 promoter repressing activity as full-length DEC1/Stra13 polypeptide, wherein reporter gene expression that is about the same indicates a DEC1/Stra13 agonists, whereas the invention of Group VIII is a method of identifying a PPARgamma2 agonist comprising: contacting a test compound with a mammalian cell comprising a functional PPARgamma2 gene; and comparing the amount of PPARgamma2 polypeptide in the presence of the test compound with the amount of PPARgamma2 polypeptide in the presence of a known PPARgamma2 agonist, wherein reporter gene expression that is about the same indicates that the test compound is a PPARgamma2 agonist.

Restriction Requirement Applicable to all Groups

Furthermore, the presence of multiple polypeptide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody. Therefore these polypeptides are patentably distinct absent factual evidence to the contrary. Rejoinder of all or a specified subset of the sequences is possible if Applicants provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified

sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement of a patentably distinct product, not an election of species.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, search and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652
Robert B. Mond
12-13-06